

## REMARKS

Reconsideration and allowance are respectfully requested.

Claims 15 to 20 have been canceled. New claims 21 to 29 have been added. The new claims are supported by the specification and by the claims as originally filed. The limitation of claims 21 and 26 with respect to the degree of filling of the recited bottle is supported, *inter alia*, at page 5, lines 4 to 6. Accordingly, no new matter has been added by the amendment of the claims.

### THE REJECTION UNDER 35 U.S.C. § 103(A)

The Examiner rejected canceled claims 15 to 20 as obvious over the combined disclosures of GB-1,544,260 and EP 0322134. EP 0322134 describes the sterilization of a blister package containing a polypropylene bottle in an autoclave. The Examiner argued that the disclosure of EP 0322134 would have motivated one of ordinary skill in the art to apply to the teaching of GB-1,544,260 to the sterilization of polypropylene bottles. Applicants respectfully traverse, and request reconsideration.

GB 1,544,260, is directed to the heat sterilization of sealed sachets made from laminated strip plastics films without deforming the sachets, using an autoclave that provides for counterpressure. GB 1,544,260, as acknowledged by the Examiner, does not disclose methods for the sterilization of a tube containing a laminated polypropylene foil nor the sterilization of polypropylene bottles using an autoclave without deformation of the packages, as claimed. Thus, GB 1,544,260 does not teach or suggest that polypropylene foil packages or polypropylene bottles can be treated according to the present claims without deformation. GB 1,544,260 does require that the internal volume of the flexible container to be sterilized must exceed the volume occupied by its liquid contents (1st page right col., line 79-83). This means that according to this reference air **must be** enclosed in the package during sterilization. Thus, GB 1,544,260 teaches that sachets made of laminated plastic films that contain some air can be sterilized with an autoclave without deformation. The reference is silent with respect to sterilizing packages made from polypropylene or a polypropylene foil that contain an amount of air by autoclaving.

EP 0322134 teaches the sterilization of a **completely filled** polypropylene bottle in a blister package using an autoclave. Applicants wish to point out that all of new claims 21 to 29 specifically require, *inter alia*, that when the package is filled with solution, gel, or ointment, some air must remain in the package. The teaching of EP 0322134 is in direct contradiction to this requirement. The teaching of EP 0322134 stipulates that a squeezable polypropylene bottle must be entirely filled in order to eliminate any air enclosed in the bottle before starting the sterilization because retained air would cause expansion of the polypropylene bottle followed by a dimpling (i.e., deformation) of the polypropylene after cooling (col. 4, line 49 to col. 5, line 12). That is, EP

0322134 teaches that air **must not be** enclosed in the package during sterilization in order to avoid deformation of the polypropylene bottle.

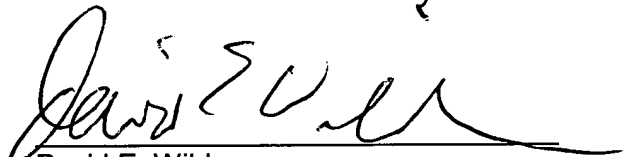
In the Office Action of June 4, 2002, the Examiner stated "The reference EP 0322134 has been relied upon to specifically teach that it is known to sterilize polypropylene bottles with a heat generating device such as an autoclave. Furthermore, if one was to use the method of GB 1,544,260 to sterilize a polypropylene bottle they would not completely fill the bottle based on the method taught by GB 1,544,260." It is respectfully submitted that the Examiner cannot disregard the teachings of EP 0322134 with regard to the effect of air in a polypropylene bottle while autoclaving. EP 0322134 does disclose sterilization of polypropylene bottles with a heat generating device such as an autoclave, **but only FULL ones**. EP 0322134 states that if you leave air in, the bottle will dimple. The presently claimed methods require the presence of air in the bottle. GB 1,544,260 is silent with respect to autoclaving polypropylene foil or polypropylene containers that contain some air, and EP 0322134 says it won't work (i.e., you get dimpling). Thus, the cited references provide no reasonable expectation of success that one could autoclave a partially full polypropylene container, and in fact predict failure.

Accordingly, it is respectfully submitted that the references cannot properly be said, alone or in combination, to render any of new claims 21 to 29 obvious.

In light of the above remarks and amendments, it is respectfully submitted that the claims are in condition for allowance, and such action is earnestly solicited.

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Respectfully submitted,



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